

CHILD-RESISTANT PACKAGING REVIEW  
Technical Review Branch

IN 11/9/2010 OUT 12/13/2010

RD, TRB, Reviewed by Rosalind L. Gross *Rosalind L. Gross* 12/13/2010

EPA Reg. No. or File Symbol 2517-RGT & 2517-RGL

DP Barcode 383875 & 383881

Decision # 425437 & 425454

EPA Petition or EUP No.

Date Division Received 10/29/10

Type Product(s) Insecticide (flea product)

Data Accession No(s). 48279600 48279601

Product Mgr./Chemical Review Mgr/Contact Person RM 10 Rosanna Louie-Juzwiak  
Division RD

Product Name(s) Sergeant's Fipronil Spot-On for Cats & Sergeant's Fipronil + S-Methoprene Spot-On for Cats

Company Name(s) Sergeant's Pet Care Products, Inc.

Submission Purpose Review of CRP studies to determine if they are adequate to support CRP certification for 2517-RGT & Review of CRP studies EPA Reg. No. 2517-RGT to determine if they are adequate to support CRP certification for 2517-RGL

Active Ingredient(s), PC code, & % Fipronil 9.7% (2517-RGT)  
Fipronil 9.8%  
S-Methoprene 11.8%

**Summary of Findings**

**In conclusion all the requirements for CRP have been met for EPA Registration No. 2517-RGT and 2517-RGL. The directions on opening the package given to consumers must be identical to those given to the seniors during testing.**

**Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.**



### Package

The package is a white plastic applicator in a rectangle of plastic. The applicator consists of three parts, which are an applicator tip, a cap, and a main chamber body. The applicator looks like a tube in a rectangle of plastic. At the top area of the applicator extending from the cap there is a narrow (needle like) applicator tip. In the rectangle of plastic surrounding the applicator in the narrow tip area there is a notch on the left and a notch on the right. The package is opened by cutting off the narrow tip area at the notches with scissors. There are three applicators with a colored stripe on each applicator label connected to each other. The color of the stripe is associated with the applicator size. The applicator, which is filled with water as a placebo, comes in a 0.5ml size for these 2 products.

The instructions given to the seniors for opening the package during CRP testing consisted of directions on a label on the back of the applicator stating "Use scissors to open." and additional instructions stating "**HOW TO OPEN:** Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors."

### Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is  $2.5\text{mg/kg} \times 11.4\text{kg}$ , which equals 28.5mg. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by  $[1030\text{mg/ml} \times 0.097 \text{ Fipronil}] = 0.285 \text{ ml} = \mathbf{0.29 \text{ ml for Fipronil only Cat product}}$  EPA REG No. 2517-RGT. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by  $[1025 \text{ mg/ml} \times 0.098 \text{ Fipronil}] = 0.284 \text{ ml} = \mathbf{0.28 \text{ ml for Fipronil \& S-Methoprene Cat product}}$  EPA REG No. 2517-RGL. Access to one applicator represents a failure for a child for all sizes equal to or greater than 0.28ml for EPA Reg. No. 2517-RGL, or 0.29ml for EPA Reg. No. 2517-RGT.



### Toxicity, Child Failure, and Package

EPA Reg #	ml (1ml = 0.0338 fl. oz.)	Fl. Oz. (29.6ml = 1 fl. oz.)	Product Density g/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt
2517-RGT	0.5	0.017	1.030	9.7	49.96	1
2517-RGL	0.5	0.017	1.025	9.8	50.23	1

#### Failure

For the purposes of CRP testing a **child failure** is access to one applicator for 0.5ml size. Access to one applicator is more than 28.5mg of Fipronil for 0.5ml size.

A **unit failure for the child test** was defined as opening the applicator or any partial or complete access to the placebo (water).

A **Senior Adult Use Effectiveness failure** is failure to access the applicator in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, not opening the applicator with scissors along the needle application tip, cutting the applicator between the cap and the body of the main chamber, cutting into the body of the main chamber of the applicator, cutting into the body of the main chamber of the applicator at other locations, cutting off the bottom of the main chamber of the applicator, or not separating a single applicator first and cutting open a second or second and third applicator.

#### Analysis of Data and Conclusion

The CRP certifications submitted May 27, 2010 for EPA Registration No. 2517-RGT and 2517-RGL **are acceptable**. The labels submitted June 29, 2010 for EPA Registration No. 2517-RGT and 2517-RGL have the same CRP directions as were used in the CRP testing.

**Child Study 3 white applicators with purple stripe on label size 0.5 ml size (MRID 48279601 Perritt 1746-001)** involved giving each child 1 set of 3 applicators connected to each other and each applicator containing 0.5 ml of water at the start of the test. A child failure was defined as access to one applicator. There were no child



failures. This study was a pass according to the child sequential test in 16 CFR 1700.20.

**Senior Adult Use Effectiveness Study 3 white applicators with purple stripe on label size 0.5 ml size (MRID 48279601 Perritt 1746-001)** involved having the test subjects open one applicator during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. **Data Analysis** showed 9 seniors failures with package A and 1 senior failure with package B, which is the maximum number of failures for a passed SAUE. The SAUE is 90%. **The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).** The number of subjects per test site was corrected such that 9 subjects (90-98) were coded as being tested at site H980 rather than site H902 (a different location within a mall, a distinction not previously made). Site H902 now is 24% of test subjects in accordance with 16 CFR 1700.20.

A bridging letter was submitted on June 30, 2010 for EPA Registration No. 2517-RGL indicating the same size and color package would be used as was tested for EPA Registration No. 2517-RGT. On the basis of that information EPA Registration No. 2517-RGL **meets the CRP test requirements** because EPA Registration No. 2517-RGT **meets the CRP test requirements**.

**For the details of each study refer to the attached summary chart (summarycht2517-135,137resubmit.doc). A failure to market these products with the identical size and color packages and fill weight colors as were tested for each size will result in these products needing to submit additional data to establish that they are CRP.**

**In conclusion all the requirements for CRP have been met for EPA Registration No. 2517-RGT and 2517-RGL. The directions on opening the package given to consumers must be identical to those given to the seniors during testing.**

**Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.**



December 13, 2010

CRPdatasummarycht

EPA REG # 2517-RGT Sergeant's Fipronil Spot On For Cats

Company Name Sergeant's Pet Care Products, Inc.

**Chemical - Fipronil 9.7%**

A **Senior Adult Use Effectiveness failure** is failure to access the applicator in the prescribed test time of 5 min. for the first package or 1 min. for the second package, not opening the applicator with scissors along the needle application tip, cutting the applicator between the cap and the body of the main chamber, cutting into the body of the main chamber of the applicator, cutting into the body of the main chamber of the applicator at other locations, cutting off the bottom of the main chamber of the applicator, or not separating a single applicator first and cutting open a second or second and third applicator.

A **child failure** is access to 1 unit. Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is opening the applicator or any partial or complete access to the placebo (water).

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x 0.097 Fipronil] = 0.285 ml = **0.29 ml for Fipronil only**  
**Cat EPA REG # 2517-RGT**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1025 mg/ml x 0.098 Fipronil] = 0.284 ml = **0.28 ml for Fipronil & S-Methoprene Cat EPA REG # 2517-RGL**

% AI - Fipronil 9.7%

**Note:**

1. The applicator is the child-resistant feature.
2. The applicators are filled in ml.
3. 10 CRP studies were submitted by the Company to cover the 5 sizes (0.5, 0.67, 1.34, 2.68, 4.02 ml) for the Fipronil only and the Fipronil and S-Methoprene products. This is based on the registrant's submission of: samples of the applicator as tested and proposed to be marketed for the Fipronil only and the Fipronil and S-Methoprene products, which appeared to be identical; and a June 30, 2010 letter indicating the same applicator color (white) and fill weight colors will be used for both the Fipronil only and the Fipronil and S-Methoprene products as was used in the CRP testing.



EPA REG #	MRID	PKG Description Include ml per Pkg  # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges  Child Get at Begin Test	Company Data		Data		Conclusion
				CRE	SAUE	Compreh ensive Review & why	Only Comp uter Analy sis	
2517-RGT Cat Fipronil only	48279601 <del>48059503</del> 1746-001	3 white applicators with purple stripe on label connected to each other. Each applicator @ 0.5ml water as placebo. <b>Tox/harm</b> = 1 applicator, <b>child fail</b> = 1 applicator	1 set of 3 applicators connected to each other.	0 child failures = Pass 50 child test		X CRE associat ed with lowest SAUE		CRP Certification 5/27/10 is acceptable. Label dated 6/29/10 same CRP directions as in study. <b>Data Analysis</b> showed no child failures. <b>Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.</b>
2517-RGT Cat Fipronil only	48279601 <del>48059503</del> 1746-001	3 white applicators with purple stripe on label connected to each other. Each applicator @ 0.5ml water as placebo. <b>Tox/harm</b> = 1 applicator, <b>child fail</b> = 1 applicator	1 set of 3 applicators connected to each other.		90% SAUE	X lowest SAUE		CRP Certification 5/27/10 is acceptable. Label dated 6/29/10 same CRP directions as in study. <b>Data Analysis</b> showed 9 seniors failures with package A and 1 senior failure with package B, which is the maximum number of failures for a passed SAUE. The SAUE is 90%. <b>The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR1700.15(b).</b> The number of subjects per test site was corrected such that 9 subjects (90-98) were coded as being tested at site H980 rather than site H902 (a different location within a mall, a distinction not previously made). Site H902 now is 24% of test subjects in accordance with 16 CFR 1700.20.



December 13, 2010

CRPdatasummarycht

EPA REG # 2517-RGL Sergeant's Fipronil + S-Methoprene Spot On For Cats

Company Name Sergeant's Pet Care Products, Inc.

**Chemical - Fipronil 9.8%**  
**S-Methoprene 11.8%**

**A Senior Adult Use Effectiveness failure** is failure to access the applicator in the prescribed test time of 5 min. for the first package or 1 min. for the second package, not opening the applicator with scissors along the needle application tip, cutting the applicator between the cap and the body of the main chamber, cutting into the body of the main chamber of the applicator, cutting into the body of the main chamber of the applicator at other locations, cutting off the bottom of the main chamber of the applicator, or not separating a single applicator first and cutting open a second or second and third applicator.

**A child failure** is access to 1 unit. Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

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Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x 0.097 Fipronil] = 0.285 ml = **0.29 ml for Fipronil only**  
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**Note:**

1. The applicator is the child-resistant feature.
2. The applicators are filled in ml.
3. 10 CRP studies were submitted by the Company to cover the 5 sizes (0.5, 0.67, 1.34, 2.68, 4.02 ml) for the Fipronil only and the Fipronil and S-Methoprene products. This is based on the registrant's submission of: samples of the applicator as tested and proposed to be marketed for the Fipronil only and the Fipronil and S-Methoprene products, which appeared to be identical; and a June 30, 2010 letter indicating the same applicator color (white) and fill weight colors will be used for both the Fipronil only and the Fipronil and S-Methoprene products as was used in the CRP testing.



EPA REG #	MRID	PKG Description Include ml per Pkg  # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges  Child Get at Begin Test	Company Data		Data		Conclusion  include CRE & SAUE via computer analysis
				CRE	SAUE	Compreh ensive Review & why	Only Computer Analysis	
2517-RGL Cat Fipronil + S- Methoprene	48279601 <del>48059503</del> 1746-001	3 white applicators with purple stripe on label connected to each other. Each applicator @ 0.5ml water as placebo. <b>Tox/harm</b> = 1 applicator, <b>child fail</b> = 1 applicator	1 set of 3 applicators connected to each other.					CRP Certification 5/27/10 is acceptable. Label dated 6/29/10 same CRP directions as in study mentioned below. <b>Size accepted based on:</b> MRID 48279601 (1746-001), EPA Reg No. 2517-RGT. <b>Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.</b> The SAUE is 90%. <b>The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR1700.15(b).</b> Bridging Letter 6/30/10 indicating same size and color package as package tested is okay.